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[REDACTED] EXAMINER

LEWIS, AARON J

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/678,580	Applicant(s) DANIEL A. JAPUNTICH ET AL.
	Examiner AARON J. LEWIS	Art Unit 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Jul 8, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 34-58 and 60-75 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 34-58 and 60-75 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 34-58,60-75 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-38,40-74,78-81 of copending Application No. 08/240,877. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in each co-pending application are drawn to a filtering face mask adapted to fit over the nose and mouth of a wearer and having an

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exhalation valve which has a flap retaining stationary surface and a second free portion which lifts away from its seat during user exhalation. While certain features (e.g. valve cover) are omitted from base claims 78 and 81 of application ('877) this feature is defined in dependent claim 37 of the ('877) application. The mere omission of an element and its function (e.g. a valve cover, the curvature of the valve seat) is an obvious expedient if the remaining elements perform the same function as before. In re Karlson, 136 USPQ 184 (CCPA 1963). Also note Ex parte Rainu, 168 USPQ 375 (Bd. App. 1969). Omission of a reference element whose function is not needed would have been obvious to one of ordinary skill in the art..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 34-36,50-56,58,60-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al.('516) in view of Shindel ('277).

As to claim 68, Simpson et al. disclose a filtering face mask that comprises: a mask body (1,2) that is adapted to fit over the nose and mouth of a wearer (fig.1); and an exhalation valve (fig.2) that is attached to the mask body, the exhalation valve comprising: a valve seat that comprises: a

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seal surface; an orifice (16) that is circumscribed by the seal surface; and a flap-retaining surface (portion abutting retainer 17); and a single flap (15) that has a stationary portion and only one free portion and a peripheral edge (i.e. the edge of the valve flap 15 as illustrated in fig.2 of Simpson et al. is readable upon the recited peripheral edge) that extends 360 degrees about the flap and that includes a stationary segment and a free segment, the stationary segment of the peripheral edge being associated with the stationary portion of the flap so as to remain at rest during an exhalation, and the free segment being associated with the one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the free segment also being located below the stationary segment when the filtering face mask is worn on a person and viewed from the front (i.e. fig.1 of Simpson et al. illustrates the face mask angled downwardly when donned; consequently, the free portion of valve flap 15 would be positioned below the stationary segment). (page 2, lines 37-50).

The difference between Simpson et al. and claim 68 is a valve cover that is disposed over the valve seat and that comprises a surface that holds the flexible flap against the flap-retaining surface such that the flap is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice under any orientation of the valve, the point where the flexible flap is mechanically held against the flap retaining surface being located off center relative to the flap.

Shindel (col.2, lines 59-66) teaches a valve securing device in the form of a valve cover (7) that is disposed over the valve seat and that comprises a surface (14) that mechanically holds

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flexible flap (6) against the flap retaining surface (5) in an abutting relationship therewith when a fluid is not passing through the orifice under any orientation of the valve, the point where the flexible flap is mechanically held against the flap retaining surface being located off center (fig.2) relative to the flap. Shindel cites the advantages of simplicity of arrangement and ready removability of the cover when desired which would allow for replacement and/or cleaning of the valve and orifices.

It would have been obvious to modify the manner of attachment of the exhalation valve of Simpson et al. to employ a cover over the valve seat because it would have provided a simple arrangement with ready removability of the cover when desired and because it would have provided protection for the exhalation valve as taught by Shindel.

As to claims 34 and 35, the particular material from which the valve seat of Simpson et al. is made and the manner of making the valve seat can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular material including plastic material. It is noted that Simpson et al. (page 2, line 39) discloses the valve flap being made from a plastic material. Consequently, it is submitted that it would have been obvious to make the valve seat from any well known material (e.g. plastic) having known physical characteristics to achieve an expected result (i.e. physical cooperation of like plastic materials).

As to claim 36, the seal (fig.2) of Simpson et al. is illustrated as being substantially uniform and since the flexible flap (15) of Simpson et al. is disclosed as being made from plastic and since known physical characteristics of plastics include flexibility and resiliency, it would have been

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obvious that the flap (15) of Simpson et al. being made from plastic is "...capable of allowing the flap to display bias towards the seal surface.".

As to claim 50, while Simpson et al. is silent as to the relative surface areas of the fixed and free portions of flap (15), it is submitted that the particular relative amounts of the fixed and free portions can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular relative amounts.

As to claim 51, the flange against which the flap is secured in Simpson et al. (fig.2) is illustrated as being the same 360 degrees around the valve seat.

As to claim 52, given the downward orientation of the mask body (1,2) of Simpson et al. (fig.1) and given that any exhaled air must pass outward between the valve flap (15) and the body of the mask, it stands to reason that exhaled air will follow a path which is generally parallel to the upper surface of the body of the mask which itself is downwardly oriented as illustrated in fig.1. Therefore, exhaled air is deflected downwardly during use of the mask of Simpson et al..

As to claim 53, the mask body of Simpson et al. is cup shaped and includes at least one shaping layer and a filtration layer (page 1, lines 108-123). Simpson et al. (page 1, line 116) disclose that the shaping layer may be located on one or both sides of the filtration layer. One or both sides would include being located outside of the filtration layer.

As to claims 54-56, while Simpson et al. do not address the particular volume of a wearer's exhalation exiting the exhalation valve (12), it is submitted that since the exhalation valve (12) is expressly disclosed as opening in response to a wearer's exhalation, it would have been obvious

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that the valve would remain opened as long as a wearer is exhaling which would enable most if not all of the volume including 60-73% of gas exhaled by a wearer to pass through valve (12) of Simpson et al..

As to claim 58, since the mask body (1,2) of Simpson et al. is angled downwardly when positioned on a wearer's face, the valve (fig.2) mounted in cantilever fashion on mask body (1,2) of Simpson et al. is positioned substantially opposite a wearer's mouth (fig.1).

As to claim 60, the orifice (16) of Simpson et al. does not wholly correspond to the shape of the seal surface inasmuch as the boundaries of the orifice are set at a distance within the seal surface.

As to claim 61, the valve cover of Shindel has an opening (13) that is disposed directly in the path of fluid flow when the free portion of the flexible flap is lifted from the seal surface during an exhalation.

As to claim 62, the opening (13) in the valve cover of Shindel is approximately parallel to the path traced by the second end of the flexible flap during its opening and closing.

As to claim 63, the valve cover of Simpson et al. as modified by Shindel and its opening direct exhaled fluid flow downwards when the mask is worn on a person (see fig.1 of Simpson et al.).

As to claim 64, the valve cover of Shindel includes fluid-impermeable sidewalls (11).

As to claim 65, the opening (13) in the valve cover of Shindel is at least the size of the orifice in the valve seat.

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Claim 66 is substantially equivalent in scope to claim 33 and is included in Simpson et al. as modified by Shindel for the reasons set forth above with respect to claim 33.

As to claims 67,69, the valve cover of Shindel is secured to the valve seat by friction fit (11,15) to a wall (5,8) of the valve seat.

As to claim 70, Shindel (figs.3 and 4) illustrates the valve cover (10) having fluid impermeable sidewalls that support a fluid impermeable ceiling, and wherein the valve cover has an opening (12) that is disposed directly in the path of fluid flow, the fluid impermeable sidewalls and the ceiling and the positioning of the opening in the valve cover causing the fluid flow to be directed downwardly away from the wearer's eyes during an exhalation when the mask is worn by a person.

As to claims 71,72,75, Shindel teaches the flexible flap being mechanically clamped between the surface on the valve cover and the flap retaining surface col.2, lines 51-55 and the flap retaining surface is not disposed in the path of the exhale flow stream and outside the region defined by the plurality of openings (#16 of Simpson et al.).

As to claim 73, Simpson et al. teach a plurality of openings (16) disposed within the orifice beneath where the flexible flap (15) is mounted to the valve seat when viewing the filtering face mask from the front in an upright position.

As to claim 74, the exhaled air of Simpson et al. as modified by Shindel provide an exhalation valve which opens responsive to a wearer's exhalation. Accordingly, the exhalation valve

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constitutes a structure which is fully capable of performing the recited function of being a primary passage for a wearer's exhaled air.

5. Claims 37-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. ('516) in view of Shindel ('227) as applied to claims 34-36,50-56,58,60-75 above, and further in view of McKim ('618).

The difference between Simpson et al. as modified by Shindel and claim 37 is the flexible flap having a curved profile.

McKim teaches a valve flap having a fixed portion (14a) and a free portion (opposite the fixed portion as illustrated in figs. 1 and 3), the one free portion of the flexible flap having a profile that comprises a curve when viewed from the front, which curve is cut to correspond to the general shape of the seal surface. McKim teaches a curved seal surface and curved flexible flap for the purpose of seating quickly, effectively and without float or bounce after each opening (col. 1, lines 64-72).

It would have been obvious to further modify flexible valve flap and seat of Simpson et al. (fig. 2) to make it curved because it would have provided quick seating, in an effective manner and without float or bounce after each opening as taught by McKim.

As to claims 38-39, the flap (15) of Simpson et al. is disclosed as being made from plastic and/or rubber. The physical characteristics of plastic and rubber include elasticity. Consequently, the particular material from which the valve flaps of Simpson et al. are made can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any

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particular elasticity of such a material. One of ordinary skill would recognize the need for routine experimentation and observation in an effort to arrive at a range of elasticities of such valve flaps which would be open and close responsive to a wearer's exhalation and cessation of exhalation in a manner which protects the wearer.

As to claims 40 and 41, the degree of seal between the valve flap and valve sealing surface of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular degree of seal including one meeting the standards as set forth in 30CFR 11.183-2, July 01, 1991. Further, it stands to reason that one of ordinary skill would strive to make a face mask in accordance with at least minimum current government standards of operation and including a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hrs. at 70 degrees centigrade.

As to claims 42-46,48,49, the particular dimensions, the particular material including the hardness of the material of the flexible flap (15) of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular dimensions nor in any particular constituency. One of ordinary skill would recognize the need for experimentation and observation of physical characteristics and parameters in the development of the flexible flap because it would have to have those physical parameters which would cause it to be responsive to a wearer's exhalation in a manner which would also protect the wearer.

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As to claim 47, the one free portion of the flexible flap (see fig.3 of McKim) of Simpson et al. as further modified by McKim has a profile that comprises a curve when viewed from the front, which curve is cut to correspond to the general shape of the seal surface.

Response to Arguments

6. Applicant's arguments filed 07/08/2002 have been fully considered but they are not persuasive.

The Castiglione affidavit contends that the valve flap of Simpson et al. must rely of negative inhalation pressure to maintain a closed position is disagreed with because there is no disclosure in Simpson et al. which suggests such a requirement. On the contrary, Simpson et al. fig.3 clearly illustrates valve flap (14) being resiliently held in a closed position against knife edge sealing surfaces (19) thereby providing a clear teaching of a seal between the valve flap and valve seat during before the mask is donned. Further, Simpson et al. (page 1, lines 39-64 and page 2, lines 29-32) disclose that the mask is intended to filter harmful vapors (a function which cannot be accomplished while an exhalation valve is dangling open), that the mask includes an exhalation valve(s) located on portion (1, upper side) and/or portion (2, lower side) of the mask, that the exhalation valve(s) are intended to materially reduce the buildup of water vapor and that while the exhalation valve(s) may leak it is clear from the disclosure that they are not intended to leak. Therefore, in view of the the disclosure as a whole, one of ordinary skill could not conclude that the exhalation valve(s) of Simpson et al. would require negative inhalation pressure in order to remain in a closed position.

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Applicant's assertion that the exhalation valve flap would dangle open responsive to gravitational forces even if accurate does not distinguish from Simpson et al. because if the exhalation valve of fig.2 were located within portion #1 (upper portion) of the mask as illustrated in fig.1 and as disclosed by Simpson et al. at page 2, lines 29-32, then by applicant's own reasoning the valve flap would remain in the closed position due to gravitational forces until being subjected to the pressure of exhalation by a wearer.

The Affidavit of David M. Castiglione is insufficient to overcome the above prior art rejection because: the declaration provides no objective evidence that the valve of fig.2 of Simpson et al. cannot remain closed without negative pressure within the mask based upon an actual physical inspection and comparison of the prior art device (Simpson et al.) to the device of the instant invention as claimed. Affiant concludes that the valve of fig.2 requires negative pressure within the mask in order to remain closed based upon a reading of the specification of Simpson et al. rather than on actual objective testing of the prior art device.

Applicant's assertion that the statement given by the examiner for combining the prior art to Simpson et al. and Shindel is inadequate because it merely constitutes a reason why one of ordinary skill might have used the cover of Shindel is disagreed with. It is submitted that the reasoning given by the examiner constitutes proper motivation as to why one of ordinary skill would have been motivated to combine the prior art.

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Applicant's arguments regarding the age of the Shindel device are noted; however, it is submitted that the relative ages of the prior art references do not preclude the combining of the references in the manner set forth above in the grounds of the rejection.

As to the Bowers affidavit, the argument that McKim constitutes nonanalogous art because it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, it is submitted that one of ordinary skill would look to the art of valves (which includes McKim ('618)) to address problems associated with the effectiveness of valve seating of a valve element which is used for controlling the direction of flow of breathable air through such a valve. McKim clearly addresses the problem of effectiveness of valve seating by non-aligning the flap retaining surface and the seal surface relative to each other thereby providing effective seating without float or bounce after each opening (col.1, lines 64-72).

Applicant's argument that the valve of McKim lacks the required flexibility of applicant's invention is noted; however, it is submitted that the valve of Simpson et al., being an exhalation valve, exhibits structure which is fully capable of providing such a function. Further, no particular degree of flexibility is quantitatively and/or structurally defined in any of the claims of the instant application.

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Applicant's arguments that the prior art does not provide the benefits of applicant's invention is disagreed with because the prior art does teach the claimed structure of the instant application and as such, is fully capable of providing the so called benefits.

Applicant's argument that the propriety of the combination is not proper is disagreed with because the reasons for modification of Simpson et al. are clearly set forth above in the body of the rejection(s) of the claims.

Accordingly, the Bowers Affidavit is insufficient to overcome the prior art rejection set forth herein above based upon a conclusion that they do no believe that one of ordinary skill would be motivated to combine the teachings of McKim with Simpson et al. to achieve the valve of the instant invention. It is submitted that one of ordinary skill having possession of the prior art to Simpson et al. and McKim which clearly teaches nonaligned mounting of a valve flap in order to achieve effective sealing would suggest an answer to the problem of how to prevent accidental valve opening and efficient sealing between inhalation and exhalation.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Lewis whose telephone number is (703) 308-0716.

Aaron J. Lewis

September 30, 2002



Aaron J. Lewis
Primary Examiner